JC04 Rec'd PCT/PTO 2 1 JUN 2001

FORM PTO-1390 (REV. 11-2000) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY 'S DOCKET NUMBER	
6969	
U S APPLICATION NO (If known, see 37 CFR 1 5)	
09/868882	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/GB99/03811	17 November 1999	24 December 1998

TITLE OF INVENTION
Transdermal Drug Delivery System

APPLICANT(S) FOR DO/EO/US
Solomon, Montague Cecil; Tocili, Biljana; Solomon, David,Louis,Charles

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [XX] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [XX] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [XX] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [XX] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [XX] is attached hereto (required only if not communicated by the International Bureau).
   b. [ ] has been communicated by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [XX] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [XX] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [XX] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [XX] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [XX] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [ ] Other items or information:

531 Rec'd P[illegible] 21 JUN 2001

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
09/868882		

21. ☐ The following fees are submitted:	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1000.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$860.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860	00
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130	00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		x **$18.00**	$	
Independent claims	- 3 =		x **$80.00**	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$270.00**	$	
TOTAL OF ABOVE CALCULATIONS =				$ 990	00
☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2. +				$ 495	00
SUBTOTAL =				$ 495	00
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE =				$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
TOTAL FEES ENCLOSED =				$ 495	00
				Amount to be refunded:	$
				charged:	$495.00

a. ☒ A check in the amount of $ 495.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-0040. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Martin Faier, Esq.
Faier & Faier P.C.
566 W. Adams St., Suite 600
Chicago, IL 60661

SIGNATURE

Martin Faier
NAME

20,294
REGISTRATION NUMBER

TITLE

Transdermal Drug Delivery Systems

DESCRIPTION

Technical Field

The invention relates to transdermal drug delivery systems, that is systems for the administration of medicine through the skin of a patient and into the systemic circulation. In this way, the medicine avoids passing through the gastro-intestinal tract and liver. Thus metabolism is to some extent avoided, and a smaller dose can be used.

Background Art

GB 2249956 contains a useful summary of the state of the art, and discloses such systems containing super-saturated solutions of an active ingredient within an adhesive layer by use of a carefully selected mixture of solvents.

THE INVENTION

The invention provides a method of manufacturing a transdermal drug delivery system which comprises dissolving a pharmaceutically active substance in a ratio less than saturation level in a solvent which is also a skin penetration enhancer, and mixing the resulting solution with an adhesive in the form of an aqueous dispersion or solution. By using the active substance in a ratio less than saturation level, there is a reduced risk of crystallization, a stable system can be manufactured, and a constant rate of delivery to the patient obtained.

It is surprising that certain solvents act both as a skin penetration enhancer and as a solvent for the active substance. Such solvents/enhancers include crotamiton, diethyltoluamide (DEET) and mixtures of two or more thereof. The ratio of crotamiton to diethyltoluamide in such a solvent mixture may be from 5:95 to 95:5% by weight of the total solvent/enhancer content depending on the delivery rate and extent of delivery required for the active substance. By choosing a solvent/enhancer or solvents/enhancers having a boiling point higher than any drying temperature applied to the system, and controlling the drying temperature, the solvent(s) do not evaporate, the solution of the active substance never becomes saturated, and a high proportion of

active substance remains in the system. The active substance/solvent(s) solution can be maintained at 20°-30°C for over one month.

The system is generally presented on a backing sheet and protected up to use by a release liner.

The pharmaceutically active substance may be:
α-Adrenergic agonists such as Adrafinil, Adrenolone, Amidephrine, Aproclonidine, Clonidine, Ephedrine, Naphasoline and Tramazoline;
ß-Adrenergic agonists such as Albuterol, Clenbuterol, Clorprenaline, Methoxyphenamine and Terbuterol;
α-Adrenergic blockers such as Amosulalol, Dapiprasol, Ergoloid Mesylates, Prazosin, Terazosin, Yohimbine;
ß-Adrenergic blockers such as Acebutolol, Alprenolol, Atenolol, Pindolol, Propanolol and Timolol;
Anabolics such as Androstenediol, Ethylstrenol, Methandriol, Nandrolone, Oxymesterone, Quinbolone and Stenbolone;
Analgesic (narcotic) such as Alfentanil, Benzylmorphine, Buprenorphine, Codeine, Codeine Phosphate, Dihydrocodeine, Dihydromorphine, Fentanyl, Methadone Hydrochloride, Morphine, Morphine Derivatives, Narceine, Opium, Oxycodone, Oxymorphone, Phenazocine and Sufentanil;
Analgesics (non-narcotic) such as Acetaminophen, Acetanilide, Acetylsalicyclic Acid, Carbamazepine, Diflunisal, Indomethacin, Ketoprofen, Naproxen, Phenacetin, Salicylamide and Tramadol;
Androgens such as Mesterolone, 17-Methyltestosterone, Testosterone and Testosterone Propionate;
Anaesthetics such as Amylocaine Hydrochloride, Bupivacaine, Lidocaine, Midazolam, Procaine, Tetracaine Hydrochloride, Thiopental Sodium and Zolamine;
Anti-acne drugs such as Algestone Acetophenide, Benzoyl Peroxide, Cyproterone, Resorcinol, Retinoic Acid and Tetroquinolone;
Anti-amebic such as Chloroquine, Chlortetracycline, Dehydroemetine, Emetine, Teclosan, Thiocarbamizine and Tinidazole;
Antianginals such as Alprenolol, Amlodipin Diltiazem, Felodipine, Isosorbide Dinitrate, Nicardipine, Nifedipine, Nitroglycerin, Oxprenolol, Pindolol, Timolol and Verapamil;

Antibacterial drugs such as Gentamicin, Kanamycin, Neomycin, Chloramphenicol, Chloramphenicol Pantothenate, Clindamycin, Lincomycin, Clarithromycin, Erthromycin and Cycloserine;
Anti-estrogens such as Delmadinone Acetate, Tamoxifen and Toremifene;
Antifungal drugs such as Clotrimazole, Econazole, Ketoconazole, Miconazole and Potassium Iodide;
Antihistamines such as Chlorpheniramine, Dimethindene, Pheniramine, Triprolidine and Phenothiazine;
Antihypertensive drugs such as Captopril, Enalapril, Clonidine and Minoxidil;
Anti-inflammatory drugs such as Mefenamic Acid, Flubiprofen, Ibuprofen, Indomethacin, Ketoprofen, Aspirin, Mesalamine, Olsalasine, Piroxicam and Tenoxicam;
Anti-parkinsonian drugs such as Amantadine, Levodopa, Pergolide and Pridinol;
Antipyretics such as Camphor, Menthol, Phenol, Polidocanol, Spirit of Camphor and Trimeprazine;
Anti-seborrheic drugs such as Pyrithione, Resorcinol, Selenium Sulphides and Tioxolone;
Antiseptics such as Chlorhexidine, Bismuth Iodide Oxide, Povidone Iodine, Triclosan, Triclosane Potassium, Carvacrol, p-Cresol, Chloroxine, Halquinol, Boric Acid, α-Terpineol and Chlorhexidine;
Anti-ulcerative drugs such as Cimetidine, Enprostil, Omeprasol, Ranitidine and Trimoprostil;
Anxiolytic drugs such as Buspirone, Bromazepam, Diazepam, Loxapine, and Meprobamate;
Chlorinergic agents such as Bethanechol Chloride, Physostigmine and Pyridostigmine Bromide;
Depigmentors such as Hydroquinine, Hydroquinone and Monobenzone;
Estrogens such as Benzestrol, Dienestrol, Diethylstilbestrol, Dimestrol, Methestrol, Conjugated estrogenic Hormones, Equilenin, Equilin, Estradiol, EstradiolBenzoate, Estradiol 17ß-Cypionate, Estriol, Estrone, Ethinyl Estradiol, Mestranol, Moxestrol, Quinestradiol and Quinestrol;
Gonadotropic hormones such as LH and PMSG;
Nootropic agents such as Aceglutamide, Antiracetam, Piracetam, Pyritinol and Tacrine.
Progestogens such as Allylestrenol, Anagestone, Chlormadinone Acetate, Delmadinone Acetate, Demegestone, Desogestrel, Dimethisterone,

Dydogesterone, Ethisterone, Ethynodiol, Flurogestone Acetate, Gestodene, Gestodene Caprolate, Haloprogesterone, 17-Hydroxy-16-methylene-progesterone, 17*α*-Hydroxyprogesterone, 17-*α*-Hydroxygesterone Caprolate, Lynestrenol, Medrogestone, Medroxyprogesterone, Megestrol Acetate, Melengestrol, Norethisterone, Norethisterone Acetate, Noretynodrel, Norgesterone, Norgestimate, Norgestrel, Norgestrienone, Norvinistyerone, Pentagestrone, Progesterone, Promegestone, Quingestrone and Trengestone;
Respiratory stimulants such as Almitrine, Doxapram, Lobeline, Sodium Succinate and Tacrine;
Vitamins, vitamin sources and vitamin extracts such as Vitamins A, B, C, D, E and K and derivatives thereof, Calciferols, Glycyrrhiza and Mecobalamin; or
Vulnerary agents such as Acetylcysteine, Allantoin, Asiaticoside, Cadexomer Iodine, Chitin, Dextranomer and Oxaceprol.

The solvent/enhancer can be Crotamiton, Diethyltoluamide (DEET), Transcutol (Diethylene glycol monoethyl ether), Labrafil MI944CS (unsaturated polyglycolysed glycerides), Labrasol (Glyceryl and polyethylene glycol esters), Tea-tree oil (Oil of Melaleuca), Propylene Glycol, MP DIOL (2-Methyl-1,3- Propanediol) or Polyetheylen Glycol.

It will be appreciated that the amount of active substance to be incorporated in the delivery system is dependent or governed by the drug composition and/or concentration, the desired therapeutic effect for a patient, and the period for which the delivery system is to provide a therapeutic drug level. Preferably, the active substance is present in an amount from 0.1% to 50% by weight of the coating material (i.e. an aqueous emulsion or adhesive solution). More preferably, 0.3% to 30% by weight of the coating material.

The adhesive can be an acrylate, silicone or polyisobutylene. The active substance is generally incorporated in the solvent/enhancer at room temperature (25°C or below) and in a ratio less than 90% of saturation level to prevent crystal formation during storage. Dissolution may be aided by sonication or warming. The resulting solution can be added slowly to the adhesive which may be in the form of an aqueous dispersion or solution, and mixed. An adhesive thickener may be added

to the mixture at about a 50% solution/water mix to produce a thicker spreading solution for reverse roll coating or knife over roll coating.

The resulting delivery system may then be coated onto a release liner, which may be a siliconised polyester such as type FL 2000 (commercially available), or paper, which naturally is impermeable to the active substance. The system can then be dried by circulating hot air, and laminated onto a backing sheet, which may be a 3M Health Care Type 1220, the backing sheet naturally being impermeable to the active substance. The layer may be coated to a wet-coat thickness of from 20 to 500μm. Alternatively, the delivery system mixture may be spread or coated onto the backing sheet, and then laminated to the release liner. The hot air circulation may be effected at gradually increased temperatures from 50°C to 140°C.

DRAWING

Fig. 1 is section through an adhesive tape for application to the skin of a patient comprising a drug delivery system according to the invention. A delivery system comprising an active substance, adhesive and solvent/skin penetration enhancer 4 is coated as a layer onto a siliconized release paper 2 and laminated onto a backing strip 6.

The following Examples of ingredients in parts by weight may be used in the production of delivery systems as described above:

	Eg 1	Eg 2	Eg 3	Eg 4	Eg 5
Estradiol Hemihydrate	1.0	1.0	1.0	1.0	0.9
Norethisterone Acetate	2.0	2.4	2.4	2.4	2.4
DEET	-	-	-	18.0	15.3
Crotamiton	-	18.0	20.0	-	2.7
Labrafil M (1944CS)	5.0	4.25	-	-	-
Transcutol	20.0	-	-	-	-
Lauroglycol	4.0	-	-	-	-
Labrasol	4.0	-	-	-	-
Monsanto 3011	64.00	74.35	-	-	-
Monsanto 2484			76.6	78.6	-
Monsanto 2397	-	-	-	-	-
C945/127		-	-	-	78.7
NS 2287	-	-	-	-	-
Acrysol ASE60	-	-	-	-	-
Ammonia BP (aq.dil)	qs	qs	qs	qs	-
Purified water (BP)	qs	qs	qs	qs	qs

	Eg 6	Eg 7	Eg 8	Eg 9	Eg 10	Eg 11
Estradiol Hemihydrate	0.9	0.9	0.9	1.2	1.1	1.0
Norethisterone Acetate	2.4	2.4	2.4	-	-	-
DEET	9.0	2.7	15.3	-	6.0	6.09
Crotamiton	9.0	15.3	2.7	7.5	0.6	-
Labrafil M(1944CS)	-	-	-	2.0	-	-
Transcutol	-	-	-	-	-	-
Lauroglycol	-	-	-	-	-	-
Labrasol	-	-	-	-	-	-
Monsanto 3011	-	-	-	-	-	-
Monsanto 2484	-	-	-	-	-	-
Monsanto 2397	-	-	-	89.3	-	-
C945/127	78.7	78.7		-	-	93.77
NS 2287	-	-	78.7	-	92.3	-
Acrysol ASE60	-	-	-	-	-	0.2-0.9
Ammonia BP (aq.dil)	-	-	-	-	-	qs
Purified water (BP)	qs	qs	-	qs	-	qs

Manufacturing Method (illustrative)

A) Delivery System using adhesive - aqueous emulsion

The active substance is dissolved in the solvent/enhancer by means of heating and mixing over a 45°-55°C water bath with agitation. When the solution is optically clear, it is checked microscopically for absence of crystals.

The adhesive is weighed into a separate mixing vessel, diluted with water if necessary over a period not exceeding 30 mins to achieve the requisite viscosity. The active substance/solvent solution is gradually added to the adhesive solution with mixing. The pH is adjusted to 6.5-7.5 and a thickener is added (if appropriate) to obtain a suitable viscosity (eg

900-1000 cps) for the selected coating process such as reverse roll coating or knife over roll coating.

The resultant aqueous emulsion is coated onto a release liner (typical coating thickness 20-500 μm), and dried by passing in sequence through ovens at 50-140°C. The product is then laminated onto a backing sheet.

B) Delivery system using an adhesive solution

The active substance is dissolved in a solvent/enhancer by means of heating and mixing as described above. The adhesive is weighed in a separate vessel and the active substance/solvent solution is gradually added to the solution of adhesive with mixing. The resultant adhesive solution is coated onto a release liner, dried by passing in sequence through ovens at 50-140°C. The product is then laminated onto a backing sheet.

In-vitro drug delivery through the skin

In-vitro skin permeation experiments with human skin have been on systems made from the above ingredients carried out using Franz-type diffusion cells, and the studies were carried out on a Hanson Microette system.

Dermatomed human skin sections were mounted onto the Franz cells and transdermal drug delivery systems mounted on tape backings (1.5cm^2) were placed on the stratum corneal surface of the skin. Each Franz cell contained 7ml of ethanol phosphate buffered saline as the receptor medium, maintained at 32°C. At predetermined time intervals 0.7ml of the receptor solution was sampled and an equal amount replaced.

The samples were analysed by High Pressure Liquid Chromatography.

The skin mass transport of Estradiol and Norethisterone Acetate has been found to be enhanced by the solvent/skin penetration enhancer DEET and/or Crotamiton in a concentration below saturation. Further, the active substance flux profile follows the solvent flux profile, the latter showing high skin penetration flux during the first 20 hours of application.

Indications

The main indications are in both peri-menopausal and menopausal women for the control in the former of the symptoms of the menopause such as hot flushes, sweating and the other symptoms of the peri-menopause, and in the case of the menopause the prevention of osteoporosis and cardiac events such as coronary thrombosis.

CLAIMS

1. A method of manufacturing a transdermal drug delivery system which comprises dissolving a pharmaceutically active substance in a ratio less than saturation level in a solvent which is also a skin penetration enhancer, and mixing the resulting solution with an adhesive in the form of an aqueous dispersion or solution.

2. A method according to claim 1 in which the solvent/enhancer includes crotamiton.

3. A method according to claim 1 or claim 2 in which the solvent includes DEET.

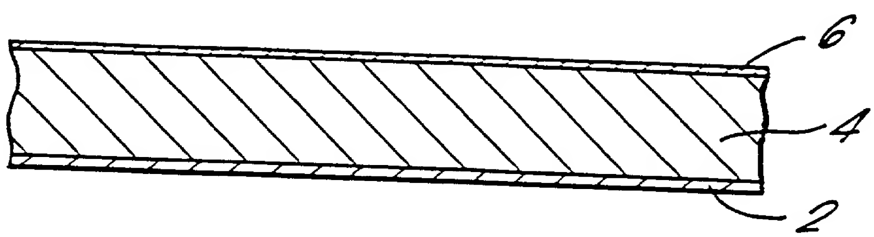
4. A method according to any preceding claim in which the active substance includes estradiol.

5. A method of manufacturing a transdermal drug delivery system substantially as herein described in any of the Examples.

6. A transdermal drug delivery system manufactured by a method according to any preceding claim.

7. A transdermal drug delivery system according to claim 6 in which the active substance is present in said aqueous dispersion or solution from 0.1% to 50% by weight.

FIG. 1.



PTO/SB/01 (03-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	6969
First Named Inventor	Solomon, Montague
COMPLETE IF KNOWN	
Application Number	
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Transdermal Drug Delivery System

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 06/21/2001 21 June 2001 as United States Application Number or PCT International Application Number PCT/GB99/03811 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

PTO/SB/01 (03-01)
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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: [XX] Customer Number or Bar Code Label [ ] OR [XX] Correspondence address below

Name	Martin Faier, Faier & Faier P.C.		
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR : [ ] A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Montague Cecil		Family Name or Surname Solomon	
Inventor's Signature M. Solomon			Date 6/8/2001
Residence: City London	State GBN England	Country UK	Citizenship UK
Mailing Address 19 St. Leonard's Terrace			
City London	State England	ZIP SW34QT	Country UK

NAME OF SECOND INVENTOR: [ ] A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Biljana		Family Name or Surname Tocili	
Inventor's Signature B. Tocili			Date 6/8/2001
Residence: City London	State GBN England	Country UK	Citizenship MK
Mailing Address 4a Ackmar Road			
City London	State England	ZIP SW64UP	Country UK

[ ] Additional inventors are being named on the ____supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

Please type a plus sign (+) inside this box → ☐

PTO/SB/02A (11-00)
Approved for use through 10/31/2002. OMB 0651-0032
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DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 1 of 1

3-00

PTO/SB/02A (11-00)

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
David Louis Charles	Solomon

Inventor's Signature [signature] Date: 16th August 2001

Residence: City	State	Country	Citizenship
London GBN	England	UK	UK

Mailing Address: 84a Philbeach Gardens

Mailing Address:

City	State	ZIP	Country
London	England	SW5 (GB)	UK

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature: Date:

Residence: City	State	Country	Citizenship

Mailing Address:

Mailing Address:

City	State	ZIP	Country

Name of Additional Joint Inventor, if any: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname

Inventor's Signature: Date:

Residence: City	State	Country	Citizenship

Mailing Address:

Mailing Address:

City	State	ZIP	Country

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